

## **REMARKS**

### **I. Claim Amendments**

Independent claims 1, 3, 10 and 18 have been amended as suggested by the examiner on page 5 of the final Office Action to include the limitation that the recited rAAV-producing cell is modified with an additional expression cassette encoding AAV Rep 52 and Rep 40 proteins but not AAV Rep 78 and Rep 68 proteins. These amendments are supported throughout the “Summary of Invention” (such as at page 4, line 22 through page 5, line 11; page 5, lines 18-20; page 5, line 31 through page 6, line 6; and page 6, lines 32-28) and by the examples. Dependent claim 11 has been canceled in view of the amendment to claim 10. Claim 1 has also been amended to correct the clerical error discussed in Section II below. The amendments do not introduce new matter.

### **II. The Rejection Under 35 U.S.C. § 112, Second Paragraph Should be Withdrawn**

Claims 1, 2 and 22-38 were rejected under 35 U.S.C. § 112, second paragraph because the phrase “said rAAV-producing cell insert” purportedly lacked antecedent basis. The inclusion of the word “insert” was an inadvertent clerical error. The word “insert” has been deleted from claim 1. Therefore, the rejection under 35 U.S.C. § 112, second paragraph is moot and should be withdrawn.

### **III. The Rejection Under 35 U.S.C. § 102 Should be Withdrawn**

The rejection of claims 1-3, 10-13, 18, 21, 23, 24, 30, 32 and 33 under 35 U.S.C. § 102(b) as allegedly being anticipated by Natsoulis *et al.* (U.S. 6,027,931) was maintained in the final Office Action. In response, as noted in Section I above, Applicants have adopted the Examiner’s suggestion on page 5 of the final Office Action to include a claim limitation that the recited rAAV-producing cell is modified with an additional expression cassette encoding AAV Rep 52 and Rep 40 proteins but not AAV Rep 78 and Rep 68 proteins in order to distinguish the prior art. Therefore, the rejection under 35 U.S.C. § 102 should be withdrawn.

**IV. The Rejection under 35 U.S.C. § 103(a) Should Be Withdrawn**

The Examiner maintained the rejection of claims 22, 26, 28, 29, 31, 35, 37 and 38 under 35 U.S.C. § 103(a) as being unpatentable over Natsoulis *et al.* (U.S. Patent No. 6,027,931) in view of Hardy (U.S. Patent No. 6,429,001). The Examiner stated that Hardy teaches that AAV host cells include the claimed cell types: HeLa, WI-38, MRC-5 and Vero.

Similarly, claims 25 and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Natsoulis *et al.* in view of Murphy (U.S. Patent No. 6,635,476). The Examiner stated that Murphy teaches that the PERC.6 cells line is useful for producing adenovirus and rAAV.

Claims 27-29 and 36-38 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over Natsoulis *et al.* in view of Potash *et al.* (U.S. Patent No. 5,911,998). The Examiner stated that Potash *et al.* teaches that the MRC-5, WI-38 and FRhL-2 cell lines may be used for vaccine production.

In addition, the Examiner rejected claims 4, 5 and 8 under 35 U.S.C. § 103(a) as being unpatentable over Natsoulis *et al.* in view of Collaco *et al.* (*Gene* 238:397-405, 1999). The Examiner stated that Collaco teaches the production of rAAV using pSH3 and pSH5 vectors that comprise E4, E2a and VA genes.

The Examiner also rejected claims 9, 14 and 19 under §103(a) as being unpatentable over Natsoulis *et al.* in view of Collaco (*Gene* 238:397-405, 1999) and in further view of Gao *et al.* (U.S. Patent No. 7,235,393). The Examiner asserted that Gao *et al.*, teaches that any available adenovirus would be useful for production of rAAV, including those from simian species such as SV-35 and SV-25.

Since the primary document, Natsoulis *et al.*, underlying the rejections does not teach or suggest the subject matter of the amended claims, combinations of it with other documents that fail to teach or suggest the claimed subject matter do not render the claims obvious. Therefore, the rejections under 35 U.S.C. § 103(a) should be withdrawn.

**CONCLUSION**

In view of the foregoing amendment and remarks, Applicants believe the pending claims are in condition for allowance and early notice thereof is requested. If further discussion would expedite allowance of the claims, the Examiner is respectfully requested to contact the undersigned at the telephone number below.

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Respectfully submitted,

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